DEC 2 6 2000

X. 510(k) Summary K003050

Name of Device

Trade name:	CryoGen Cryosurgical System 3
Common name:	Cryosurgical Unit and Accessories
Classification name:	Cryosurgical Unit and Accessories (21 CFR 878.4350)

Predicate devices

CryoGen Cryosurgical System 1	K964971
CryoGen Cryosurgical System 2	K972662
CryoGen Cardiac Cryosurgical System	K974320
Frigitronics CE-4 & CE-4G	Pre-Amendment
Frigitronics CCS 100	K811390
CMS AccuProbe	K904421
CMS AccuProbe 550/530	K953637

Device description & Principle of Operation

The CryoGen Cryosurgical System 3 consists of three components: the disposable Control Unit, the Cryoprobe and the Console, which contains the compressor system, microprocessor and user interface. The Cryogen FirstOption Cryosurgical System is a cryosurgical device incorporating a gas cooled cryoprobe. Operation of the System is based on the Joule-Thomson principle in which pressurized coolants are expanded through a small orifice to produce cooling. The device is intended to destroy tissue by the application of extreme cold. Temperatures of -80 to -100 °C are developed at the tip of the cryoprobe. These temperatures are within the range of the predicate devices and is sufficient to achieve the desired tissue effect. None of the coolant comes into contact with the patient or physician. In addition, none of the coolant gases are exhausted into the atmosphere, the system is closed. There is no cooling along the shaft of the probe nor at the handle that is held by the user during treatment.

Intended use

The CryoGen Cryosurgical System 3 is intended to ablate soft tissue by the application of extreme cold in minimally invasive or endoscopic surgical procedures in the areas of general surgery, urology, gynecology, pulmonary and thoracic surgery.

Technological characteristics

The technological characteristics of the CryoGen Cryosurgical System 3 are the same as those of the CryoGen Cryosurgical Systems 1 & 2, the CryoGen Cardiac System and the other predicates listed within this premarket notification. These devices are substantially equivalent in terms of design, materials, principle of operation, product specifications and sterilization.

Summary

By virtue of design, materials, function and intended use, the CryoGen Cryosurgical System 3 is substantially equivalent to the CryoGen Cryosurgical Systems 1 and 2, as well as the CryoGen Cardiac System, all devices cleared for marketing under the Premarket Notification process. It is also equivalent to the predicate devices distributed by other manufacturers, both pre-amendment and cleared via the Premarket Notification proces.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 6 2000

Ms. Cheryl Shea
Vice President, Regulatory Affairs, Quality Assurance
and Clinicals
CryoGen, Inc.
11065 Sorrento Valley Court
San Diego, California 92121

Re: K003050
Trade Name: CryoGen Cryosurgical System 3
Regulatory Class: II
Product Code: GEI
Dated: September 29, 2000
Received: October 2, 2000

Dear Ms. Shea:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the performance of cryoablation of the endometrium have not been established.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for

Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Kimber C. Richter for

Bernard E. Statland,M.D.,Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: CryoGen Cryosurgical System 3
510(k) Number: K003050

Indications for use:

The CryoGen Cryosurgical System 3 is intended to ablate soft tissue by the application of extreme cold in the areas of general surgery, urology, gynecology, pulmonary and thoracic surgery using a minimally invasive or endoscopic approach.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003050 12/12/00

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)